

Appl. No. : 09/435,562
Filed : November 8, 1999

REMARKS

With this amendment, Claims 38, 51-53, 55-57, 60, 77-82 and 101 have been amended, and Claims 129-135 have been added. Claims 38-45, 51-98, 101 and 106-135 are thus presented for further examination.

Information Disclosure Statement

Applicant notes that the references submitted in the Information Disclosure Statement of October 21, 2003 were not indicated as considered by the Examiner in the Office Action mailed January 30, 2004. Applicant respectfully requests that the Examiner consider and/or check off these references.

Objection to Claim 38

The Examiner objected to Claims 38-45 because of certain informalities. Applicant has amended Claim 38 in accordance with the Examiner's suggestion, and respectfully requests that the rejection be withdrawn.

Rejections Under 35 U.S.C. § 102 and 103

The Examiner has rejected Claims 38-40, 51, 53, 55-58, 62-63, 66-69, 72, 75, 83-86, 89, 92, 94, 101, 106 and 109 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,124,523 to Banas. The Examiner has rejected Claims 61, 64-65, 70-71, 73-74, 76, 87-88, 90-91, 93 and 108 under 35 U.S.C. § 103(a) as unpatentable over Banas in view of U.S. Patent No. 5,853,422 to Huebsch. The Examiner has rejected Claims 95-98 under 35 U.S.C. § 103(a) as unpatentable over Banas in view of Huebsch and further in view of U.S. Patent No. 5,108,474 to Riedy. The Examiner has rejected Claims 38-45, 51-94, 101 and 106-109 under 35 U.S.C. § 103(a) as unpatentable over Huebsch in view of Banas. The Examiner has rejected Claims 95-98 under 35 U.S.C. § 103(a) as unpatentable over Huebsch in view of Banas and further in view of Riedy.

Claim 38-45 and 61-76

Claim 38, as amended, is directed to a containment device for positioning at a left atrial appendage, comprising, inter alia, at least three supports each comprising an elongate, flexible element, in which at least a portion of the element is inclined toward an intermediate portion

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between proximal and distal ends of the device. When in this orientation, the intermediate portion of the device is sized and configured to engage a surface at the left atrial appendage.

Banas is directed to an encapsulated cylindrical stent for providing a smooth surface to support laminar flow of blood through the encapsulated stent. As noted by the Examiner, Banas discloses the expandable stent with two ends of the stent flared outward toward the ends. Accordingly, Applicant submits that Banas fails to teach or suggest the unique combination of features recited by Claim 38.

Applicant further submits that Huebsch, which is directed to a septal defect closure device, fails to teach or suggest the specific structure recited by Claim 38. In particular, the Huebsch device, which is directed to span both sides of a septal defect, would be inappropriate to position at a left atrial appendage for containing the left atrial appendage, and would not have an intermediate portion sized and configured to engage a surface at the left atrial appendage, as claimed. Therefore, Applicant requests that the Huebsch be withdrawn.

Applicant submits that the structure recited by Claim 38 is also not suggested by a combination of Huebsch with Banas, nor is there any motivation to combine the disclosure of a septal defect closure device in Huebsch with the disclosure of a stent in Banas to arrive at Applicant's claimed invention. Neither Huebsch nor Banas discloses a structure suitably sized and configured for engaging a surface at the left atrial appendage, nor does either reference teach or suggest the unique characteristics of the membrane itself. Moreover, Banas in fact teaches away from providing an endothelialization membrane to promote tissue in-growth, as it instead describes as advantageous a membrane surface that is inert, smooth and non-thrombogenic. Col. 3, lines 1-10. Such a membrane would be incompatible with a device wherein it is desired to promote endothelialization.

For the foregoing reasons, Applicant requests that the rejection of Claim 38 be withdrawn. With respect to dependent Claims 39-45 and 61-76, Applicant submits that each of these claims recites a unique combination of features not taught or suggested by the cited art, and that the rejections of these claims should also be withdrawn.

Claims 51-60 and 77-98

Claim 51 as amended recites, *inter alia*, a containment device for implantation at an opening in the body, comprising, *inter alia*, a support member extending from a proximal end and

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inclining radially outward to an apex portion, and then inclining radially inward to a distal end. As discussed above, Banas discloses a device having an expandable stent, where the two ends of the stent are flared outward toward the ends, and thus, does not teach or suggest this structure. Furthermore, neither Huebsch, which discloses a septal defect closure device that spans both sides of an opening, nor Riedy, individually or in combination with each other or with Banas, teach or suggest this structure. Applicant further submits that dependent Claims 52-60 and 77-98 each recites a unique combination of features not taught or suggested by the cited art. Accordingly, Applicant respectfully requests that the rejection of Claim 51-60 and 77-98 be withdrawn.

Claims 101 and 106-109

Claim 101 is directed to a device for implantation within a left atrial appendage of a patient comprising, *inter alia*, an endothelialization membrane attached to at least a proximal face of the device having a pore size sufficient to permit endothelialization, the proximal face of the device comprising at least in part the inclined portion of a plurality of the flexible elements and being sized and configured to block an opening to the left atrial appendage.

Applicant respectfully submits that neither Banas nor Huebsch, individually or in combination, teach or suggest the unique combination of features recited by Claim 101. In particular, neither Banas nor Huebsch contains any teaching or suggestion whatsoever for an inclined portion sized and configured to block an opening to the left atrial appendage. Furthermore, with respect to the claimed porosity in the range of about 5 to about 60 microns, Applicant submits that Banas only discloses *initial* internodal distances. At column 13, lines 43-47, Banas states: "The ePTFE grafts preferably comprise *initial* internodal distances (INDs) within a range of 10-90 microns" (emphasis added). However, there is no discussion of *final* internodal distances or final porosity. Presumably, by specifying an initial IND, Banas recognizes that the IND changes during the stent graft manufacturing process. It is presumptuous to assume that the Banas process produces a porosity of about 5 to about 60 microns.

Accordingly, Applicants respectfully submit Claim 101 is in condition for allowance. Applicant further submits that dependent Claims 106-109 each recites a unique combination of features not taught or suggested by the cited art, and that these claims are also in condition for allowance.

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New Claims

Applicant has added new Claims 131-135. Applicant respectfully submits that these claims are allowable over the cited art of record.

CONCLUSION

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims pursuant to statutory sections 102, 103 and/or 112, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of these amendments and remarks, reconsideration and withdrawal of the outstanding rejections is respectfully requested.

Any claim amendments which are not specifically discussed in the above remarks are not made for patentability purposes, do not narrow the claims, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Rather, these amendments have only been made to increase claim readability, to improve grammar, and to reduce the time and effort required of those in the art to clearly understand the scope of the claim language.

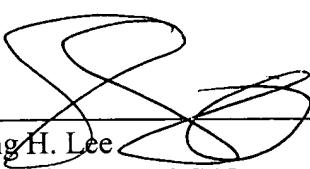
If the Examiner has any questions which may be answered by telephone, he is invited to call the undersigned directly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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